SOP Number: GCP 02
SOP NAME: Qualified Investigative Personnel and Sites
Effective Date: 4-Jan-2016 (rev 7-Jun-2023)

1. POLICY

The purpose of this Standard Operating Procedure (SOP) is to define and clarify the responsibilities of the NIH StrokeNet Regional Coordinating Centers (RCCs), the National Coordinating Center (NCC), and the National Data Management Center (NDMC) in the management of performance sites (PS). The Protocol Principal Investigator (PPI) and/or designee is considered by the United States Food and Drug Administration (US FDA) to be a trial's "sponsor-investigator" should such a role be required for the protocol. The PPI is responsible for identifying qualified PSs (inside or outside of the NIH StrokeNet network) and qualified site personnel.

2. DEFINITIONS AND ABBREVIATIONS

GCP	Good Clinical Practice
HSP	Human Subjects Protection
NCC	National Coordinating Center at the University of Cincinnati
NCC-MPI	NIH StrokeNet Multiple Principal Investigator
NCC-PM	StrokeNet Project Manager – coordinator of StrokeNet site, who is responsible for providing and or verifying training and general oversight for NIH StrokeNet projects conducted at the Clinical Trial Performance Site
NDMC	National Data Management Center – located at the Medical University of South Carolina
PPI	Protocol Principal Investigator – Principal Investigator who is awarded the NIH StrokeNet site grant and has oversight of NIH StrokeNet projects conducted at the Clinical Trial Performance Sites
PPM	Protocol Project Manager- coordinator associated with the funded protocol who is responsible for developing and providing personnel training in collaboration with the NCC PM and the PPI
PS	Performance Site - clinical location that serves as execution site for a clinical trial
PS-PI	Performance Site Principal Investigator
PS-SC	Performance Site Study Coordinator
RCC	NIH StrokeNet Regional Coordinating Center
RCC-PI	RCC Principal Investigator who provides oversite to trials executed in the RCCs network
US FDA	United States Food and Drug Administration

3. SCOPE

This SOP has been developed to ensure compliance with Federal regulations and Good Clinical Practice (GCP) guidelines, as set forth in the 1996 ICH E6 Consolidated Guidance manual. The policies and procedures in this SOP apply to parties involved with NIH StrokeNet research, including the NCC, the NDMC, all RCCs and all PSs.

4. PROCEDURES

The NIH StrokeNet NCC Principal Investigator (NCC-PI) and NIH StrokeNet NCC Project Manager (NCC-PM) provide general oversight for each NIH StrokeNet trial conducted in the network in collaboration with the particular trial PPI.

A. Responsibilities of the NCC-MPI, PPI, and NCC-PM and CPM regarding Qualified Investigative personnel and sites.

- Identify qualified PSs from inside and outside the network with appropriate personnel, necessary equipment and sufficient patient volume to successfully recruit and execute the clinical trial.
- Identify all training and credentialing required for PS research staff to conduct the funded clinical trial.
- Provide PS staff with access to the required training and credentialing and verify upon completion.
- Provide assistance and oversight to each RCC so they may facilitate the completion of required training and credentialing by PS research staff.
- Provide assistance and oversight directly to PS staff that are NOT affiliated with a specific RCC to facilitate the completion of required training and credentialing.

B. Responsibilities of the RCC-PI and RCC Manager regarding Qualified Investigative personnel and sites.

- Facilitate the completion of required training and credentialing by PS research staff.
- Oversee the electronic maintenance of required training and credentialing documentation in WebDCU™.

C. Responsibilities of the PS-PIs and PS-SC

PS-PI responsibilities:

- Confirm that each staff member is qualified to perform study specific tasks that have been delegated to her/him, and document staff training and qualifications on the study specific Delegation of Authority Log for the purposes of ICH, FDA and CIRB requirements.
- Update the Delegation of Authority Log throughout the study as needed, as well as document their supervision and involvement in the ongoing conduct of the study.

- Actively prepare for, and allow the research staff time to participate in, monitoring visits and audits.

PS-SC responsibilities:

- Coordinate trial screening and enrollment activities for the PS research staff.
- Collect required training and credentialing for PS research staff before beginning direct involvement in NIH StrokeNet study activities.

5. APPLICABLE REGULATIONS AND GUIDELINES

Code of Federal Regulations. General responsibilities of investigators: 21 CFR Parts 11, 50, 54, 56, 312 & 314. March 31, 2008.

International Conference on Harmonization Guidelines. Good Clinical Practice: Consolidated Guidelines E6; Safety E2A; General Considerations E8. March 31, 2008.

Guidelines for the Monitoring of Clinical Investigations. January 1988

FDA Compliance Program Guidance Manual Program 7348.811. Chapter 48-Bioresearch. February 21, 2001.

6. REFERENCES TO OTHER APPLICABLE SOPS

NIH StrokeNet GCP #12	Regulatory and Clinical Data Storage
NIH StrokeNet ADM #14	Development of Study Materials and Investigational Site Training

7. ATTACHMENTS AND REFERENCES

General FDA information:

- The FDA Home Page
- Good Clinical Practice in FDA-Regulated Clinical Trials: Includes useful guidance documents and information sheets.
- The Drug Approval Application Process

Specific FDA information:

- Information for Clinical Investigators

8. DOCUMENT HISTORY

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	21-Dec-2015	21-Dec-2015	04-Jan-2016
2.0	Review with administrative changes	08-Jun-2023	13-Jun-2023	13-Jun-2023